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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/003,674

10/23/2001

M. Michael Wolfe

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09/05/2007

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EXAMINER

ROMEO, DAVID S

ART UNIT

PAPER NUMBER

1647

MAIL DATE

DELIVERY MODE

09/05/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/003,674

Applicant(s)

WOLFE ET AL.

Examiner

David S. Romeo

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-89 is/are pending in the application.
- 4a) Of the above claim(s) 46-50, 52, 54, 56, 57, 68-72, 74, 76, 78-82, 84 and 86-89 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-45, 51, 53, 55, 58-67, 73, 75 and 77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 36-89 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Claims 36–89 are pending.

Election/Restrictions

Applicant's elected without traverse group I, claims 1–34, and the species SEQ ID NO: 2 in the paper filed 02/09/2004. Applicant's elected with traverse the species "dispersing" and "normal saline" in the paper filed 02/09/2004. The requirement was still deemed proper and was therefore made FINAL.

Claims 46–50, 52, 54, 56–57, 68–72, 74, 76, 78–82, 84 and 86–89 are directed to an invention that is independent or distinct from the invention originally claimed for the reasons set forth in the Office action mailed 12/14/2006. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 46–50, 52, 54, 56–57, 68–72, 74, 76, 78–82, 84 and 86–89 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 36–45, 51, 53, 55, 58–67, 73, 75 and 77 are being examined to the extent that they are directed to SEQ ID NO: 2, a dispersing agent and normal saline.

Claim Objections

Claims 83 and 85 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Since claim 85 depends from claim 83 it also shares this defect. Accordingly, the claims have not been further treated on the merits.

Claims 40, 42–45, 59 and 62–67 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The polypeptide of claims 40 and

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42–45 could be infringed without infringing the polypeptide of claim 36. The polypeptide of claims 59 and 62–67 could be infringed without infringing the polypeptide of claim 58.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

5 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10 The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15 Claims 37, 40–45, 59 and 62–67 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Support for the 95% identity limitation and the indicated amino acid substitutions cannot be found in the disclosure as originally filed. The introduction of these
20 limitations raises the issue of new matter.

Applicant argues that:

25 In fact, rat and human GIP have the same function, differing only in a single amino acid at position 18 of SEQ ID NO:2. The difference is his/arg, each considered an equivalent to the other. This is support for the different equivalent substitutions claimed by Applicants in the 7-30 and 10-30 GIP amino acid segments.

30 Applicant's arguments have been fully considered but they are not persuasive. The fact that rat GIP differs from human GIP by a single amino acid at position 12 of SEQ ID NO:2 (the difference is his/arg) may support a his/arg substitution at this position. However, the claims are directed to or encompass replacement of his at position of 12 of SEQ ID NO: 2 with arginine or lysine. While it might be obvious to a skilled artisan to substitute his at position 12 of SEQ ID NO: 2 with lysine, the written description does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. It extends only to that which is disclosed. One shows that one is in possession of the invention by describing the invention,
35 with all its claimed limitations, not that which makes it obvious. Therefore, the his/arg

difference between rat and human GIP does not evince that applicant considered a lysine substitution at position 12 of SEQ ID NO: 2 as part of the invention.

Applicant argues that:

5 The comparable rat/human GIP activity also supports a claim to a 95% identity to the 7-30 and 10-30 GIP segments because of the single difference between rat and human GIP.

10 Applicant's arguments have been fully considered but they are not persuasive. The 95% identity to the 7-30 and 10-30 GIP segments encompasses variants that differ anywhere and everywhere from the rat or human GIP within the metes and bounds of the 95% identity limitation. Therefore, the scope of the 95% identity limitation is broader than a single his/arg substitution at position 12 of SEQ ID NO: 2, changes the meaning, scope and content of the disclosure, introduces new concepts, and violates the description requirement of the first paragraph of 35 U.S.C. 112.

15 Claims 37, 39, 41, 58-59 and 61 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

20 Claim 37 is indefinite over the recitation of "95% identical to corresponding consecutive amino acids of SEQ ID NO: 2" because it is unclear if the claimed polypeptide is 95% identical to SEQ ID NO: 2 or if it is 95% identical to some indeterminate number of consecutive amino acids of SEQ ID NO: 2. The metes and bounds are not clearly set forth. If applicant wants to claim a polypeptide that is 95% identical to SEQ ID NO: 2 it is suggested that the claim recite "95% identical to SEQ ID NO: 2." Claim 59 also shares this defect and is rejected on these same grounds and for the same reasons that claim 37 is rejected.

25 Claim 41 is indefinite because there is a lack of antecedent basis for "the neutral amino acid" and because it is unclear which neutral amino acid is intended. The metes and bounds are not clearly set forth.

30 Claim 58 is indefinite over the recitation of "a contiguous amino acid sequence from position 4-24 of SEQ ID NO: 2" because it is unclear if the claimed polypeptide comprises amino acids 4-24 of SEQ ID NO: 2 or if it comprises an indeterminate fragment of contiguous amino acids 4-24 of SEQ ID NO: 2. The metes and bounds are not clearly set forth. If applicant

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wants to claim a polypeptide comprising amino acids 4-24 of SEQ ID NO: 2 it is suggested that the claim recite "An isolated polypeptide comprising amino acids 4-24 of SEQ ID NO: 2.

Claims 39 and 61 are indefinite because it is unclear if the claimed polypeptide comprises or consists of SEQ ID NO: 2. The metes and bounds are not clearly set forth.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 36, 55, 58 and 77 are rejected under 35 U.S.C. 102(b) as being anticipated by Moody (FEBS Lett. 1984 Jul 9;172(2):142-8) in view of Takeda (Proc Natl Acad Sci U S A. 1987 Oct;84(20):7005-8).

15

A 35 U.S.C. 102 rejection over multiple references has been held to be proper when the extra references are cited to:

- (A) Prove the primary reference contains an "enabled disclosure;"
- (B) Explain the meaning of a term used in the primary reference; or
- (C) Show that a characteristic not disclosed in the reference is inherent.

20

Moody discloses the isolation of human GIP 1–42 and a freeze-dried (lyophilized) form thereof (page 142, Abstract; page 144, left column, last full paragraph). Although Moody discloses the sequence of human GIP as Tyr-Ala-Glu-Gly-Thr-Phe-Ile-Ser-Asp-Tyr-Ser-Ile-Ala-Met-Asp-Lys-Ile-His-Gln-Gln-Asp-Phe-Val-Asn-Trp-Leu-Leu-Ala-Glu-Lys-Gly-Lys-Lys-Asn-Asp-Trp-Lys-His-Asn-Ile-Thr-Gln (page 142, Abstract), which differs from SEQ ID NO: 2 by the substitution of a Glu for a Gln at position 23 of SEQ ID NO: 2, Moody also indicates the amino acid sequence of human GIP as Tyr-Ala-Glu-Gly-Thr-Phe-Ile-Ser-Asp-Tyr-Ser-Ile-Ala-Met-Asp-Lys-Ile-His-Gln-Gln-Asp-Phe-Val-Asn-Trp-Leu-Leu-Ala-Gln-Lys-Gly-Lys-Lys-Asn-Asp-Trp-Lys-His-Asn-Ile-Thr-Gln (page 146, Fig. 5), which comprises the amino acid sequence of SEQ ID NO: 2. Moody further indicates that residue 29 is Gln, which corresponds to the Gln at position of 23 of SEQ ID NO: 2. Furthermore, Takeda discloses the predicted amino acid sequence of mature GIP, which comprises the amino acid sequence of SEQ ID NO: 2 (page 7007, Fig 3). Takeda indicates that the predicted

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sequence of GIP agrees exactly with that determined by Moody (page 7006, sentence bridging left and right columns).

Accordingly, Moody discloses an isolated polypeptide comprising the amino acid sequence of SEQ ID NO: 2 and a lyophilized form thereof.

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Claims 45 and 67 are rejected under 35 U.S.C. 102(b) as being anticipated by Agerberth (Eur J Biochem. 1993 Sep 1;216(2):623-9).

Agerberth discloses the isolation of GIP (7-42) (paragraph bridging pages 624-625. GIP (7-42) comprises the amino acid sequence of SEQ ID NO: 2 wherein the histidine at position 12 of SEQ ID NO: 2 is replaced with arginine (page 628, Fig. 7).

10

Claims 37 and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by Gelling (Regul Pept. 1997 Apr 30;69(3):151-4).

Under 35 U.S.C. 120, the claims in a U.S. application are entitled to the benefit of the filing date of an earlier filed U.S. application if the subject matter of the claim is disclosed in the manner provided by 35 U.S.C. 112, first paragraph in the earlier filed application.

15

Under 35 U.S.C. 119 (e), the claims in a U.S. application are entitled to the benefit of the filing date of a provisional application if the corresponding provisional application supports the claims in the manner required by 35 U.S.C. 112, first paragraph.

20

The 95% identity limitation violates the description requirement of the first paragraph of 35 U.S.C. 112, as discussed above. Therefore, the subject matter of claims 37 and 59 is not entitled to the benefit of the filing dates of any of the earlier filed applications.

25

Gelling teaches porcine GIP₁₀₋₃₀, ₆₋₃₀, and ₇₋₃₀ antagonistic peptides (Abstract). Twenty-three of the 24 amino acids of porcine GIP₆₋₃₀ that correspond to SEQ ID NO: 2 are identical to SEQ ID NO: 2. Therefore, Gelling discloses an GIP antagonist that is at least 95% identical to corresponding consecutive amino acids of SEQ ID NO: 2. Twenty of the 21 amino acids of porcine GIP₆₋₃₀ that correspond to amino acids 4-24 of SEQ ID NO: 2 are identical to amino acids 4-24 of SEQ ID NO: 2. Therefore, Gelling discloses an GIP antagonist that is at least 95% identical to corresponding consecutive amino acids at positions 4-24 of SEQ ID NO: 2.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 36, 51, 53, 58, 73 and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moody (FEBS Lett. 1984 Jul 9;172(2):142-8) in view of Takeda (Proc Natl Acad Sci U S A. 1987 Oct;84(20):7005-8) as applied to claims 36 and 58 above, and further in view of Turco ("Intravenous Admixtures", Chapter 85, in, Remington's Pharmaceutical Sciences, 18th edition (June 1990), Mack Pub. Co., Easton, Pennsylvania, page 1570).

Moody in view of Takeda discloses an isolated polypeptide comprising the amino acid sequence of SEQ ID NO: 2 and a lyophilized form thereof, as discussed above. Moody also discloses that GIP could be of use in at least some diabetics (page 142, paragraph bridging left and right columns). Takeda discloses that the elucidation of the primary structure of the human GIP precursor now allows examination of the biosynthesis and physiological properties of this interesting hormone in more detail. In particular, it will be important to critically address its possible role in the regulation of plasma glucose levels and its utility in the treatment of diabetes through its ability to stimulate insulin secretion. See page 7008, left column, last paragraph. Moody in view of Takeda do not disclose, only in the sense that Moody in view of Takeda do not anticipate, a composition comprising human GIP in a pharmaceutically acceptable carrier.

Turco teaches that proper electrolyte concentration and balance in plasma and tissues are critical for proper body function and that the electrolytes in normal saline more closely approximate the composition of the extracellular fluid than solutions of any other single salt (page 1570, column 2, bottom). Turco does not teach a pharmaceutical composition comprising human GIP and normal saline.

However, it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to make a human GIP, as taught by Moody in view of Takeda, and to modify that teaching by making a composition comprising human GIP in normal saline (a

pharmaceutically acceptable carrier), with a reasonable expectation of success. One of ordinary skill in the art would be motivated to make this modification because GIP could be of use in at least some diabetics, because such a composition would allow one to examine the physiological properties of GIP in more detail and address its possible role in the regulation of plasma glucose levels and its utility in the treatment of diabetes, and because the electrolytes in normal saline more closely approximate the composition of the extracellular fluid than solutions of any other single salt. To the extent that the GIP is dissolved or dispersed in normal saline, then normal saline is a dispersing agent. The invention is prima facie obvious over the prior art.

Double Patenting

Claims 58–61, 67, 73, 75 and 77 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1–5 of U. S. Patent No. 7,091,183. It is acknowledged that applicant believes that the rejection may be overcome with a terminal disclaimer, and that applicant respectfully defers a response until claims in each application are resolved.

New Formal Matters, Objections, and/or Rejections:

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 36–45, 51, 53, 55, 58–67, 73, 75 and 77 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1–21 of copending Application No. 11/504,217, over claims 1–8, 10 and 15–20 of copending Application No. 11/504,218, over claims 1–9 and 11–14 of copending Application No. 11/504,224, over
5 claims 1–10 and 12–21 of copending Application No. 11/504,526, over claims 1 and 8–21 of copending Application No. 11/504,535, and over claims 1–7 and 12–19 of copending Application No. 11/504,821. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the instant application and each of the claims in the copending applications are directed to or encompass the same peptides.

10 This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowable.

15 ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (571) 272-0890. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 9:00 A.M. TO 5:30 P.M. IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, MANJUNATH RAO, CAN BE REACHED AT (571)272-0939.

20 IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE CENTRAL FAX NUMBER FOR OFFICIAL CORRESPONDENCE, WHICH IS (571) 273-8300.

25 CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING MAY BE OBTAINED FROM THE PATENT APPLICATION INFORMATION RETRIEVAL (PAIR) SYSTEM. STATUS INFORMATION FOR PUBLISHED APPLICATIONS MAY BE OBTAINED FROM EITHER PRIVATE PAIR OR PUBLIC PAIR. STATUS INFORMATION FOR UNPUBLISHED APPLICATIONS IS AVAILABLE THROUGH PRIVATE PAIR ONLY. FOR MORE INFORMATION ABOUT THE PAIR SYSTEM, SEE [HTTP://PAIR-DIRECT.USPTO.GOV](http://PAIR-DIRECT.USPTO.GOV). CONTACT THE ELECTRONIC BUSINESS CENTER (EBC) AT 866-217-9197 (TOLL-FREE) FOR QUESTIONS ON ACCESS TO THE PRIVATE PAIR SYSTEM,

30
/DAVID ROMEO/
PRIMARY EXAMINER
ART UNIT 1647

35 DSR
AUGUST 27, 2007